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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,313

09/25/2006

Hyung Joon Cha

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JHK LAW

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EXAMINER

HA, JULIE

ART UNIT

PAPER NUMBER

1654

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/599,313	CHA ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,21,24-31,33-43 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18, 21, 24-31, 33-43, 46-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9, 39-43, 46-47 and 49, drawn to an adhesive protein comprising an amino acid sequence shown in SEQ ID NO:6 and an adhesive comprising an adhesive protein.

Group 2, claim(s) 10-18, 21 and 24, drawn to a polynucleotide comprising a nucleotide sequence encoding an adhesive protein.

Group 3, claim(s) 25-31, 33, drawn to a method of producing an adhesive protein comprising the steps of (a) constructing a vector that comprises operably a nucleotide encoding the adhesive protein, (b) constructing a transformant by transforming the vector into a host cell, and (c) producing recombinant adhesive protein by culturing the transformant.

Group 4, claim(s) 34-38, drawn to a method of purifying adhesive protein comprising the steps of (d) lysing the transformant, centrifuging it to isolate each of the supernatant and pellet, (e) making a suspension by adding acidic organic solvent to the pellet and suspending it, (f) centrifuging the suspension to isolate the supernatant.

Group 5, claim(s) 48, drawn to a method of adjusting the adhesion force of the adhesive wherein the method comprises a step of treating with a substance or a step of controlling the concentration of the adhesive protein which is an active component of the adhesive.

2. The inventions listed as Groups 1 to 5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Group 1, an adhesive protein comprising an amino acid of SEQ ID NO: 6 is disclosed in GenBank Accession No. AAS00463 (submitted Jan 2004). The GenBank

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discloses that this is a foot protein -5 [*Mytilus galloprovincialis*] (filed with IDS, 12/5/2007). Therefore, the unity of invention is broken. Therefore, Groups 1 through 5 do not relate to a single general inventive concept under PCT Rule 13.1.

Election of Species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(Different peptide for improving a physicochemical property)-Different amino acid sequences: AKPSYPPTYK (SEQ ID NO: 25) or 6 histidine residues;

Different adhesive protein sequences: SEQ ID NO: 10, 12, 14, 16, 18, 20, or 22;

Different adhesive protein: for example, SEQ ID NO: 6;

Different mussel adhesive protein: For example, SEQ ID NO: 6;

Different physicochemical property: solubility, adhesion force, cross-linking, improvement in protein expression, purification, or recovery rate;

Different nucleotide sequences: SEQ ID NO: 5, 11, 13, 15, 17, 21, 26, 27, 28, 29, 30 or 31;

Different transformant: prokaryotes, eukaryotes, or eukaryote-derived cells;

Different eukaryote-derived cells: plant, insect, or mammalian cells;

Different organic solvent: acetic acid, citric acid, or lactic acid;

Different substrate: plastic, glass, metal, eukaryotic cells, prokaryotic cells, plant cell walls, or lipids;

Different material: (genera) surfactant, oxidant or filler;

Different filler: collagen, hyaluronic acid, chondroitin sulfate, elastine, laminine, caseine, hydroxyapatite, albumin, fibronectin, or hybrin.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Claims 3, 6, 7, 9, 13, 14, 15, 17, 18, 21, 24, 27, 30, 31, 33, 36, 39, 40, 41, 43, 46, 48.

The following claim(s) are generic: Claim 2, 4, 5, 8, 12, 16, 25, 28, 29, and 34.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different peptides for improving a physicochemical property of the adhesive protein are patentably independent and distinct due to the different amino acid content, leading to different structures. For example, SEQ ID NO: 25 has the sequence AKPSYPPTYK; a peptide having 6 histidine residues will have HHHHHH sequence. Further, search for one would not necessarily lead to the other. Different adhesive proteins are patentably independent and distinct due to different amino acid content, leading to different structure. For example, first 25 amino acid residues of SEQ ID NO:12 has the sequence SSEEYKGGYYPGNSNHYHSGGSYHG...and first 25 amino acid residues of SEQ ID NO: 18 has the sequence MGGSHHHHHHGMASAKPSYPPTYKA... These peptides have different amino acid content, thus have different structures. Further, search for one

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would not necessarily lead to the other. Different adhesive proteins are patentably independent and distinct due to their different amino acid content, leading to different structures. For example, adhesive protein *Pasteurella multocida* has 343 amino acid residues (see GenBank Accession No. ABM97415). Adhesive plaque matrix protein [*Mytilus coruscus*] has 872 amino acid residues (see GenBank Accession No. BAA09850, filed with IDS). Further, search for one would not necessarily lead to the other. Different mussel adhesive proteins are patentably independent and distinct due to their different amino acid content, leading to different structures. For example, foot protein 2 [*Mytilus edulis*] has 429 amino acid residues (see GenBank AAX23972). Foot protein 1 [*mytilus edulis*] has 125 amino acid residues (see GenBank AAX23969). Further, search for one would not necessarily lead to the other. Different physicochemical properties of the protein are patentably independent and distinct. For example, solubility determines how well a protein solubilizes in a given solvent; adhesion force determines how well a protein adheres to certain surface. Further, search for one would not necessarily lead to the other. Different Nucleotide sequences are patentably independent and distinct due to different nucleic acid contents, leading different structure. For example, SEQ ID NO: 23 has the sequence GGTACCCGAATTCTGAATTCTGCTAAACCG; SEQ ID NO: 24 has the sequence GGTCTGACTCAAGCTTATCATTTGTAAGTCG. Further, search for one would not necessarily lead to the other. Different transformants are patentably independent and distinct due to the source of the transformant. For example, prokaryotes and eukaryotes are patentably independent and distinct one from the other. Further, search for one would not necessarily lead to the other. Different eukaryote-derived cells are patentably independent and distinct due to their different properties. For example, insect cells and mammalian cells require different reagents and feeding source. Further, search for one would not necessarily lead to the other. Different organic solvents are patentably independent and distinct due to their distinct structures, and properties. For example, acetic acid has the molecular formula CH_3COOH , and the melting point is 16.5°C and boiling point is 118.1°C . Lactic acid has the molecular formula $\text{C}_3\text{H}_6\text{O}_3$, and the melting point is 53°C and boiling point is 122°C . Further, search for one would not necessarily lead to the other. Different substrates are patentably independent and distinct due to their different structures and properties. For example, metal, such as silver has the chemical symbol Ag, and has melting point of 961.78°C and a boiling point of 2162°C . Lipids are fat-soluble molecules, such as cholesterol. Further, search for one would not necessarily lead to the other. Different materials are patentably independent and distinct due to their distinct structures. For example, a surfactant are wetting agents that lower the surface tension of a liquid, such as a detergent. An oxidant is an oxidizing agent that readily transfers oxygen atoms, such as peroxides. Further, search for one would not necessarily lead to the other. Different fillers are patentably independent and distinct due to their different structures. For example, collagen is a protein having 316 amino acid residues (see GenBank Accession No. CAA35954). Albumin is a protein having 609 amino acid residues (see GenBank Accession No. AAA98797). Further, search for one would not necessarily lead to the other.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

7. If Group 1 is elected, Applicant is required to elect a single disclosed species of an adhesive protein, peptide for improving a physicochemical property, physicochemical property, substrate, and a material. For example, Applicant elects adhesive protein (where adhesive protein is derived from), SEQ ID NO:10, wherein the peptide for improving a physicochemical property is 6 repeats of SEQ ID NO: 25, solubility for physicochemical property, plastic, filler that is elastine. If Group 2 is elected, Applicant is required to elect a single disclosed species of a polynucleotide sequence encoding SEQ ID NO: 6, the polypeptide sequence encoding peptide of improving physicochemical property, and the transformant. If Group 3 is elected, Applicant is required to elect a single nucleotide sequence encoding SEQ ID NO: 6, transformant, the peptide sequence of peptide (if peptide, elect a peptide sequence; if nucleotide sequence encoding the peptide sequence, then elect a nucleotide sequence) that improves a physicochemical property, they physicochemical property. If Group 4 is elected, Applicant is required to elect a single disclosed species of nucleotide encoding the sequence of the peptide, nucleotide sequence encoding an adhesive protein, transformant and organic solvent. If Group 5 is elected, Applicant is required to elect a single disclosed species of an adhesive protein and a species of material (oxidant, filler or surfactant (all are genera)).

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8. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

10. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

14. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result

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in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is (571) 272-5982. The examiner can normally be reached on 5:30 a.m. to 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julie Ha/
Examiner, Art Unit 1654